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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/582,975

06/15/2006

Eric Jervis

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EXAMINER

KETTER, JAMES S

ART UNIT

PAPER NUMBER

1636

MAIL DATE

DELIVERY MODE

11/24/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/582,975	Applicant(s) JERVIS ET AL.	
	Examiner James S. Ketter	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-76,80-108 and 111-119 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 22-33,35-76,80-93,95-108 and 111-119 is/are allowed.
- 6) ☒ Claim(s) 1,4,7-10,12,13,15-18,34 and 94 is/are rejected.
- 7) ☒ Claim(s) 2,3,5,6,11,14 and 19-21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/15/06</u> . | 6) <input type="checkbox"/> Other: _____ |

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Applicant's election without traverse of Group I in the reply filed on 22 August 2008 is acknowledged.

Claims 2, 3, 5, 6, 11, 14 and 19-21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 22-33, 35-76, 80-93, 95-108 and 111-119 are allowed.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 7-10, 13 and 15-18 are rejected under 35 U.S.C. 102(a) as being anticipated by Taylor et al. (reference 5 on the IDS filed 15 June 2006).

Claim 1 is drawn to a method of cell culture comprising: confining a cell between first and second barriers, said barriers spaced at a distance comparable to the size of said cell to contact said cell and prevent said cell from traveling toward or away from each of said first and second barriers; placing one or more spacers between said first and second barriers to prevent said first and second barriers over-compressing said cell; and providing to said cell a culture substance. Claim 4 specifies in claim 1 that each of said barriers has one or more characteristics

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selected to mimic the characteristics of the biological niche of said cell. Claim 7 specifies within claim 1 that said first and second barriers comprise first and second plates. Claim 8 specifies within claim 1 that a monolayer of cells are cultured between said barriers. Claim 9 specifies within claim 8 that the method further comprises removing a cell from said monolayer of cells when said cell to be removed is observed to meet one or more pre-determined criteria. Claim 10 specifies within claim 9 that said one or more criteria are related to one or more of karyotype, morphology, and size. Claim 13 specifies within claim 2 that said introducing comprises introducing a suspension of said cell and said one or more spacers between said first and second barriers. Claim 15 specifies within claim 1 that said cell is confined between a surface of said first barrier and a surface of said second barrier, each surface selected to limit adhesion of said cell to said each surface. Claim 16 specifies within claim 1 that said one or more spacers are configured to, with said first and second barriers, define a space having a shape mimicking the shape of the biological niche of said cell. Claim 17 specifies within claim 1 that said providing comprises flowing said culture substance to said cell at a predetermined rate. Claim 18 specifies within claim 7 that said plates are optically transparent.

At Figure 1, Taylor et al. teaches a substrate made of PDMS which has 3 micron deep grooves for the culture of neurons. Taylor et al. also teaches, e.g., generally at page 1552, that cells were plated onto the substrate with a glass coverslip to create a covered compartment. See also page 1553, first paragraph of "III. Results and Discussion." The grooved substrate and the coverslip are taught as being coated with poly-lysine. The 3 micron depth would be a design criterion with consideration of cell size.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 12, 16, 34 and 94 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claims 4 and 16, the phrases “characteristics of the biological niche” and “shape of the biological niche” are of unclear metes and bounds, as any characteristic might be included. For example, a trivial but real property of biological cells (i.e., those surrounding the cell in question when in situ) is that they are made of matter. However, the recited barriers in the claim are also made of matter, in all conceivable embodiments, and as such, it would appear that no barrier would thus be excluded from the scope of the claims. Thus, it is not clear what limitation was actually intended, rendering the metes and bounds of the claims unclear.

With respect to claim 12, the claim is structured such that “cells...are selected to provide selected surfaces”. However, this appears to be merely circular, imparting no clear limitation to the claimed invention, rendering the claim confusing.

With respect to claims 34 and 94, the claim recites “polystyrene, porous glass, or other contact lens materials.” However, if polystyrene and porous glass are contact lens material, then their separation from the genus [other] contact lens materials is confusing, as it implies that these two recited materials might be distinct from said genus. If they are meant to be distinct, however, then their inclusion by the word other is incorrect. Either way, the scope and meaning of the claim is unclear.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to James S. Ketter whose telephone number is 571-272-0770. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JSK

21 November 2008

/James S. Ketter/

Primary Examiner, Art Unit 1636